K140147

APR 2 2 2014

510(k) Summary

For

BCT Antimicrobial Dressing & BCT Silver Bandage

1. Submission Sponsor

Bio-medical Carbon Technology Co., Ltd.
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Taichung City
40755, Taiwan
Phone: +886-4-2355-4588
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Contact: Jui-Hsing Lin, Manager, R&D Center

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Dr. Diane Sudduth, Senior Consultant, QA
Email: project.management@emergogroup.com

3. Date Prepared

January 17, 2014

4. Device Identification

Trade/Proprietary Name:	BCT Antimicrobial Dressing also marketed as KoCarbon Ag Antimicrobial Dressing BCT Silver Bandage also marketed as KoCarbon Ag Silver Bandage
Common/Usual Name:	Antimicrobial Dressing
Classification Name:	Dressing, Wound, Drug
Classification Regulation:	Unclassified; 21 CFR § 878.4020*
Product Code:	FRO*
Classification Panel:	General and Plastic Surgery
Performance Standards:	No applicable performance standards have been established under Section 514 of the FD&C Act. Biocompatibility tests were done in conformance with relevant requirements of ISO 10993.

*A final classification for "Dressing" has not been implemented; however, a Class II classification has been proposed by the General and Plastic Surgery Devices Panel. At this time however, Classification Code FRO is unclassified.

5. Legally Marketed Predicate Device(s)

K022483 – ACTISORB Silver 220 Antimicrobial Binding Dressing (Johnson & Johnson Medical, Ltd.)

6. Device Description

BCT Antimicrobial Dressing consists of polyethylene terphthalate (PET) non-woven, silver-coated activated carbon fiber cloth and polyethylene (PE) film. BCT Silver Bandage contains the same ingredients, but includes an adhesive layer. The dressings and bandages contain 100 $\mu g/cm^2$ of silver and are available in several sizes to accommodate different wound sizes.

BCT Antimicrobial Dressing and BCT Silver Bandage absorbs wound fluid and exudates containing infectious organisms into the dressing fabric, where the silver exerts its antimicrobial action. The silver ions act locally within the dressing, eliminating the absorbed bacteria and pathogens.

The activated carbon fiber cloth in BCT Dressings absorbs bacterial toxins and offensive odors.

The dressings are individually packaged in a pouch. All dressings are sterile and are for single use only.

7. Indication for Use Statement

The BCT Antimicrobial Dressing & BCT Silver Bandage dressings are intended for the management of wounds and to provide an antimicrobial barrier. These dressings are applied topically and are in direct contact with the wound. Both are intended to be used for indications such as:

- Partial and full thickness wounds;
- Pressure ulcers;
- Diabetic ulcers;
- Surgical wounds;
- Acute wounds (1st and 2nd degree burns)

8. Substantial Equivalence Discussion

The BCT Antimicrobial Dressing & BCT Silver Bandage have similar indications for use and technological characteristics as Johnson & Johnson's ACTISORB Silver 220. Both dressings and bandage are manufactured with non-absorbable polymer materials and an activated carbon fiber layer and are available in a similar range of sizes. The biocompatibility testing showed comparable safety profile of the BCT Antimicrobial Dressing & BCT Silver Bandage and the predicate. Bench testing demonstrated that the devices are substantially equivalent for the management of wounds and to provide an antimicrobial barrier. See Table 5A for a comparison of characteristics.

Table 5A – Comparison of Characteristics

Manufacturer	**Bio-medical Carbon Technology Co., Ltd.**	**Johnson & Johnson Medical, LTD.**
Trade Name	BCT Antimicrobial Dressing & BCT Silver Bandage	ACTISORB Silver 220
510(k) Number	Pending	K022483
Product Code	FRO	FRO

Manufacturer	**Bio-medical Carbon Technology Co., Ltd.**	**Johnson & Johnson Medical, LTD.**
Trade Name	BCT Antimicrobial Dressing & BCT Silver Bandage	ACTISORB Silver 220
Regulation Number	None	None
Regulation Name	Dressing, Wound, Drug	Dressing, Wound, Drug
Intended Use/ Indications for Use	For the management of partial and full thickness dermal ulcers, pressure ulcers, diabetic ulcers, acute wounds such as 1st and 2nd degree burns and surgical wounds.	ACTISORB Silver 220 Antimicrobial Binding Dressing provides an effective barrier to bacterial penetration and for adsorbing offending odor resulting from wounds; the binding properties of the dressing trap bacteria, bacterial toxins and odor. ACTISORB Silver 220 Antimicrobial Binding Dressing may help reduce infection in partial and full thickness wounds, including: • Pressure ulcers • Venous ulcers • Diabetic ulcers • First and second-degree burns • Donor sites • Surgical wounds ACTISORB Silver 220 Antimicrobial Binding Dressing is suitable for use under compression bandaging.
Antimicrobial Activity Microbes tested-	S. aureus E. coli C. albicans P. aeruginose S. epidermidis S. saprophyticus Multi-drug resistant P. aeruginose E. faecalis A. haemolyticus M. furfur P citrinum S. marcescens A. niger T. rubrum	S. aureus E. coli C. albicans P. aeruginose** E. faecium** E. faecalis**
Zone of Inhibition	No well-defined zone of inhibition	No well-defined zone of inhibition
Duration	Same	7 days
Biocompatibility	Same	Biocompatibility established*
Key Factor	Same	Ag

Manufacturer	Bio-medical Carbon Technology Co., Ltd.	Johnson & Johnson Medical, LTD.
Trade Name	BCT Antimicrobial Dressing & BCT Silver Bandage	ACTISORB Silver 220
Silver process	Same	Impregnation
Silver (Ag) content	100 μg/cm²	33 μg/cm²
Silver (Ag) contact wound directly?	Same	No
Non-invasive device	Same	Yes
Structure and materials	Dressing: A. Rayon and Polyester composite absorbent layer B. Activated carbon fiber cloth with silver C. Anti-adherent polyethylene film Bandage: A. Rayon and Polyester composite absorbent layer B. Activated carbon fiber cloth with silver (ACF-Ag) C. Anti-adherent polyethylene film D. Adhesive layer	Dressing: A. Nylon non-woven B. Silver-containing Plain cloth (Charcoal activated carbon with silver) C. Nylon non-woven
Sterilization	Same	Gamma

*** Stated in 510(k) Summary**

****Stated in J.R. Furr, et al J Hosp Infection (1994) 27, 201-208**

9. Non-Clinical Performance Data

The biocompatibility of BCT Antimicrobial Dressing and BCT Silver Bandage has been demonstrated through appropriate *in vivo* and *in vitro* tests on the dressings. The products have been assessed in accordance with ISO 10993 and do not introduce any additional safety risk over the predicate device ACTISORB* Silver 220 (K022483). Antimicrobial testing demonstrated greater than a 4 log reduction in microbial population under AATCC Test Method 100-2004. Testing demonstrated comparable results between BCT Antimicrobial Dressing and the ACTISORB 220 predicate device.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

Based on the indications for use, technological characteristics and performance test results, the BCT Antimicrobial Dressing & BCT Silver Bandage is substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 22, 2014

Bio-medical Carbon Technology Company Ltd.
% Ms. Diane Sudduth
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K140147
Trade/Device Name: BCT Antimicrobial Dressing & BCT Silver Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 17, 2014
Received: January 22, 2014

Dear Ms. Sudduth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140147

Device Name

BCT Antimicrobial Dressing & BCT Silver Bandage

Indications for Use *(Describe)*

The BCT Antimicrobial Dressing & BCT Silver Bandage Dressings are intended for the management of wounds and to provide an antimicrobial barrier. These dressings are applied topically and are in direct contact with the wound. Both are intended to be used for indications such as:

* Partial and full thickness wounds;

* Pressure ulcers;

* Diabetic ulcers;

* Surgical wounds;

* Acute wounds (1st and 2nd degree burns)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S